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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/405,504 | 09/23/1999 | ANDREAS STAHL | WH9721P3MC2 | 9550 |

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EXAMINER

WEGERT, SANDRA L

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1647

DATE MAILED: 10/01/2002

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/405,504

Applicant(s)

STAHL ET AL.

Examiner

Sandra Wegert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 82-123 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 97,100,101,107,110 and 111 is/are allowed.
- 6) ☒ Claim(s) 82-96,104,114 and 117 is/are rejected.
- 7) ☒ Claim(s) 98,99,102,103,105,106,108,109,112,113,115,116 and 118-123 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

The amendment filed 2 July 2002 (Paper No. 19) has been entered. Claims 73, 74, 78, 80 and 81 have been cancelled. Claims 100, 101, 104, 110, 111 and 114 have been amended. Claims 82-123 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections and/or Rejections

URL's

The objection to the disclosure for containing browser-executable code, as set forth in the previous Office Action (3/27/02, Paper 18) is *withdrawn* because Applicant removed the URL's from the Specification (7/2/02, Paper 19).

Title

The objection to the Title as set forth in the previous Office Action (3/27/02, Paper 18) is *withdrawn* due to Applicant's amendment which introduced a new Title (7/2/02, Paper 19).

Claim Objections/Rejections

35 USC § 112, first paragraph-Scope of Enablement

Claims 82-96, 104, 114 and 117 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of identifying *FATP* inhibitors for the transporter encoded by the polynucleotides of SEQ ID NO: 24 and 46, does not reasonably provide enablement for a method of identifying the ligands of *all FATP* transporters. The reasons for this rejection for Claims 82-96, 104, 114 and 117 and 118 are set forth at p. 4-8 of the previous Office Action (Paper No. 18, 3/27/02).

The specification discloses a *FATP* transporter peptide, and uses the *FATP* transporter of SEQ ID NO: 25 in assays that identify *FATP* ligands using cells recombinantly expressing SEQ ID NO: 25.

The claims recite *FATP* polypeptides, defined by functional similarity to the disclosed *FATP*, and having approximately 95% sequence similarity. There are no definitive characteristics that distinguish the claimed *FATP*'s from other polypeptides other than recited function and 95% sequence similarity. As discussed in the previous Office Action (3/27/02, Paper 18) the art shows that receptor families have members with high structural similarities but disparate functions. A paper by Smith et al. (1997, Nature Biotechnology 15:1222-1223) demonstrated that there are numerous cases in which proteins having very different functions share structural similarity due to evolution from a common ancestral gene. A paper by Brenner (1999, Trends in Genetics 15:132-133) argued against predicting function based on homology. A paper by Bisson, et al (1993, Crit Rev Biochem Mol Biol, 28:259) found no correlation

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between homology and the substrate transported in yeast transporters. Similarly, Liang et al found that only a few amino acid substitutions in glucose transporters can change substrate specificity dramatically. The Atsushi, et al paper was cited as an example where enzyme function was modified by changing select amino acids in an acyl-CoA synthetase enzyme.

Applicants reviewed the recited papers (7/2/02, Paper 19) and concluded that the references support the idea that one can predict function from homology.

Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons:

The transporters described as *FATP* transporters could potentially bind a variety of substrates or not function in the manner disclosed for the *FATP* transporter of SEQ ID NO: 25. As discussed in the recited papers, even closely-related family members sometimes work very differently and have different specific functions in organisms (Bisson, *et al*, 1993, Crit Rev Biochem Mol Biol, 28:259). The examples above serve to illustrate that one skilled in the art would not be able to predict the function of new *FATP* polypeptides, even those with high homology, without evidence from several representative examples of *FATP* transporters that function in the manner claimed.

Proper analysis of the Wands factors was provided in the previous Office Action. Due to the large quantity of experimentation necessary to determine if all possible claimed polypeptides function as *FATP* transporters, the lack of direction/guidance presented in the specification regarding the same, the absence of working examples directed to all *FATP*'s, the complex nature of the invention, and the unpredictability of predicting the function of new proteins based on

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structure, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Conclusion: Claims 82-96, 104, 114 and 117 are rejected.

Claims 97, 100, 101, 107, 110 and 111 are allowable.

Claim 118 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 98, 99, 102, 103, 105, 106, 108, 109, 112, 113, 115, 116 and 118-123 are objected to for reciting non-elected inventions.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Advisory Information


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (703) 308-9346. The examiner can normally be reached Monday - Friday from 9:30 AM to 6:00 PM (Eastern Time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SLW

9/28/02


GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600